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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,428	08/23/2001	Eugene Michael Breznock		2577

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EXAMINER

PHANIJPHAND, GWEN G

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 01/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/938,428

Applicant(s)

BREZNOCK, EUGENE MICHAEL

Examiner

Gwen Phanijphand

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Claim Rejections – 35 U.S.C. 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3, 7, 8, 11, and 13-18 are rejected under U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,129,913 to Ruppert.

Regarding claim 1, Ruppert discloses in figure 2 an apparatus adapted for cutting holes in a body vessel or hollow organ comprising a cutting blade (15), a controlled force (21) to advance the cutting blade, and an anvil (27) against which the cutting blade is advanced.

Regarding claim 2, Ruppert discloses the apparatus of claim 1 wherein the controlled force on the cutting blade is generated by a spring (col. 2, ll. 44-47).

Regarding claim 3, Ruppert discloses in figure 4 the apparatus of claim 1 wherein the controlled force (46, 46A) on the cutting blade is generated by a jackscrew with a knob (46A) for manual advance of the cutting blade (column 3, ll. 12-23).

Regarding claim 7, Ruppert discloses in column 2, ll.2-5 the apparatus of claim 1, wherein the cutting blade is rotated while being advanced toward the anvil (fig. 2, 27).

Regarding claim 8, Ruppert discloses the apparatus of claim 1 wherein the apparatus comprises a tapered tip or trocar (fig. 2, 26) to promote tissue penetration

Regarding claim 11, Ruppert discloses the apparatus of claim 9, wherein the axially disposed ridges are blunted (fig. 2, 26).

Regarding claim 13, Ruppert discloses a method for creating a hole in a hollow organ or body vessel comprising the steps of creating an incision in the hollow organ or body vessel (figure 3) at the site until the trocar point (fig. 2, 26) has completely penetrated the hollow organ or body vessel, locating a cutting blade (15) disposed about the trocar, advancing the cutting blade into the hollow organ or body vessel under controlled force (fig. 2, 21 or fig. 4, 46, 46A) until the cutting blade rests against a blunt surface (fig. 2, 27).

Regarding claim 14, Ruppert discloses in col. 2, ll. 2-5 the method of claim 13, which includes the step of rotating the cutting blade while the cutting blade is advanced toward the anvil (fig. 2, 27).

Regarding claim 15, Ruppert discloses in figure 2 an apparatus adapted for cutting holes in a body vessel or hollow organ comprising an anvil (27), a cutting blade (15) against which the anvil is advanced, and a controlled force (21) to advance the anvil.

Regarding claim 16, Ruppert discloses the apparatus of claim 15 wherein the controlled force (fig. 4: 46, 46A) is generated by manual withdrawal of the anvil against the cutting blade (column 3, ll. 12-23).

Regarding claim 17, Ruppert discloses the apparatus of claim 15 wherein the anvil is spring-loaded in a position separated from the cutting blade (col. 2, ll. 44-47).

Regarding claim 18, Ruppert discloses in the summary (col. 1, 55-68; col. 2, ll. 1-9) the apparatus of claim 15 wherein the cutting blade is rotated while the anvil is advanced toward the cutting blade.

### *Claim Rejections – 35 U.S.C. 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,129,913 to Ruppert in view of U.S. Patent No. 6,394,893 B1 to Scholz et al.

Regarding claim 4, Ruppert discloses the apparatus of claim 1 but does not disclose that the controlled force on the cutting blade is generated by a hydraulic cylinder and hydraulic pressure supply. Scholz et al., however, demonstrate in the abstract a hydraulic-actuated blade adjuster. The actuator comprises a plurality of hydraulic cylinders and a hydraulic pressure supply that moves blades into cutting position and can also retract the blades. It is advantageous to use the hydraulic system as the controlled force since it is functionally effective, can be manufactured at a low cost, and allows accurate, measurable control. It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the controlled force on the cutting blade to one operated by hydraulic cylinders and a hydraulic pressure supply since the force applied on the cutting blade can now be measured more accurately, which in turn means the physician has more control over the depth of the blade incision. The physician also uses less manual force since the force is machine controlled.

3. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,129,913 to Ruppert in view of U.S. Patent No. 5,899,122 to Court.

Regarding claim 5, Ruppert discloses the apparatus of claim 1 but does not disclose the controlled force on the cutting blade is generated by a jackscrew and an electric motor to advance the blade. Court, however, discloses in figure 3 and column 4, ll. 51-60 a force generated by a jackscrew and electric motor to advance a blade. An electrically powered force is advantageous because it provides more measurable control and less manual exertion by the user. It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the controlled force on the cutting blade to one generated by a jackscrew and electric motor because an electrically driven one would give the physician more measurable control over the force exerted on the blade and as a result, more control over the depth of incision produced by the blade.

4. Claims 6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,129,913 to Ruppert in view of U.S. Patent No. 5,314,435 to Green et al.

Regarding claims 6 and 12, Ruppert discloses the apparatus of claims 1 and 8 but does not disclose the anvil and tapered tip or trocar being fabricated from the same polymeric material. Green et al, however, disclose in column 5, lines 25-28 that all the components of the delivery system, which includes an anvil (fig. 3, 18) and a trocar (fig. 3, 20), are fabricated from polymeric materials. It is advantageous to fabricate the anvil and trocar from polymeric materials because this reduces the cost of manufacturing the system and allows more economically feasible disposal of the system after use. It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the anvil and trocar so that both were manufactured from the same polymeric material. The polymeric material allows the anvil and trocar to be flexible and thus, maneuver more easily in certain areas of the body. Manufacturing the trocar and

anvil out of polymeric material, which is commonly distributed, also reduces cost of production.

5. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,129,913 to Ruppert in view of U.S. Patent No. 4,191,191 to Auburn.

Regarding claims 9 and 10, Ruppert discloses the apparatus of claim 8, but does not disclose a trocar or tapered tip that includes axially disposed ridges that are sharp enough to cut tissue. Auburn, however discloses a trocar with axially disposed ridges capable of cutting tissue (col. 3, ll. 15-20) in figure 3. The sharp ridges of the trocar are advantageous because the physician can achieve penetration through one insertion without having to exert significant force. Previous trocars often require more force and in turn, yield undesirable deep penetration into the tissue. It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the trocar to include axially disposed ridges that capable of cutting tissue so that the physician can create a puncture with less force. The sharp ridges of the trocar also allow the physician to have more control over the depth of the penetration since the amount of applied force has more influence on the depth of the incision.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,695,581 to Lacy

U.S. Patent No. 6,402,252 B1 to Dickson

U.S. Patent No. 5,893,369 to LeMole

U.S. Patent No. 6,401,707 to Fladgard et al.

U.S. Patent No. 5, 843,113 to High

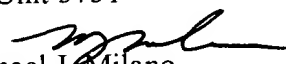
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gwen Phanijsphand whose telephone number is 703-305-4845. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

GP  
July 12, 2002

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